K003376

JAN 2 5 2001

"510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Welch Allyn Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, N.Y. 13153-0220

Contact Person & Telephone: Colin Wolff
(315) 685-2525

Date Summary Prepared: December 14, 2000

Device Name: Classification Name – Indirect Ophthalmoscope
Common/Usual Name - Ophthalmoscope
Proprietary Name - Welch Allyn 11800 Ophthalmoscope

Predicate Device: Reichert 11305 Ophthalmoscope

Device Description, Intended Use & Effectiveness:

The Welch Allyn model 11800 ophthalmoscope is a hand held indirect monocular device intended to be used by trained personnel to view the cornea and retina of a patient. The viewing path in conjunction with the large solid angle projection of the illumination path provides a larger field of view than attainable with the standard direct ophthalmoscope. The viewing optics, composed of an objective lens, relay component and eyepiece provide an erect, un-reversed image of the patients retina to the doctor.

The illumination path of the instrument consists of a filament lamp, a condensing system and a small mirror. The mirror is located slightly above the viewing path. The condensing lens images the lamps filament essentially onto the mirror. This filament image is then imaged (by the objective lens of the viewing path) onto the patient's cornea. The lamp filament, mirror and patients cornea are considered to be conjugates (or object-image pairs) to each other. The filament image at the corneal plane is small permitting an increased ease of entry into un-dilated pupils.

This instrument with its larger field of view and increased ease of entry allows for a more thorough examination of the retina while minimizing the exam and exposure time to the patient. The effectiveness of the 11800 Ophthalmoscope is the same as current monocular indirect ophthalmoscopes already on the market.

Technological Characteristics:

Criteria	Welch Allyn 11800 Ophthalmoscope
Type:	Monocular Indirect
Power Source:	3.5v
Illumination:	Halogen lamp
Viewing Optics:	Acrylic/Glass lens Combination
Image Position:	Right Side Up
Size:	7"L x 4"H x 2"W

Weight:	½ lb
Date Introduced:	2001

Safety:

Numerous safety areas were investigated and reviewed to ensure that the Welch Allyn 11800 Ophthalmoscope is as safe, or safer than existing similar devices already in commercial distribution. The specific safety areas considered are as follows:

Toxicity - The patient eyecup is made of materials that are skin compatible –USP Grade 6.

Electrical - Agency approval based on standards from IEC601-1 & UL2601-1.

Light - Light output levels are consistent with output from similar devices in the field. Ultraviolet and infrared filtering have been incorporated into the device.

Corrosion - Device is non-corrosive.

Explosion - Highly unlikely; manufactured of non-explosive materials. Uses approved power sources already on the market.

Surface Temperature - All surfaces have been evaluated for practitioner contact.

Fire Hazard - Probability extremely low; this system uses a low voltage halogen lamp, which draws a maximum of 3.5 watts power.

Mechanical (Sharp Edges) - All contact surfaces have been blended and rounded. No injury will result from sharp edges.

Design - Risk Analysis, FMEA, and Verf.& Valid. performed for device.

Summary of Effectiveness:

The determination of device effectiveness was coordinated in the following manner:

The Welch Allyn 11800 Ophthalmoscope development team conducted on-site evaluations of the device with practicing physicians in an effort to determine if the device met all of the practitioner's needs. The evaluating practitioners were also users of either an existing Welch Allyn Ophthalmoscope, or other manufacturer's model ophthalmoscope (all have the same intended use). The results of the evaluations indicated that the Welch Allyn 11800 Ophthalmoscope serves the needs of the documentation procedure in an equivalent or better manner of effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Welch Allyn, Inc.
c/o Colin Wolff, CQE
Quality Engineer
Medical Division
4341 State Street Rd.
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K003376
Trade Name: Welch Allyn 11800 Ophthalmoscope
Regulatory Class: II
Product Code: 86 HLI; HLJ
Regulation: 886.1570
Dated: October 26, 2000
Received: October 30, 2000

Dear Mr. Wolff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Intended Use:

510(k) Number (if known): K003376

Device Name: Welch Allyn 11800 Ophthalmoscope

Indications For Use:

The Welch Allyn model #11800 Ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous, and retina of the eye. It has the same operating principles and intended use as many competitive ophthalmoscopes already in commercial distribution. The device is intended to be used by trained personnel within a medical or school environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daryl Kaufman

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003376

Prescription Use X OR Over-The-Counter Use___

(Optional Format 1-2-96)